

CLAIMS:

Accordingly, what is claimed is

1. A centrifugation configuration for centrifugally separating a composite fluid into at least one of the component fluid arts thereof, said configuration being adapted to receive a composite fluid from a fluid source and adapted to provide for the delivery of at least one separated fluid component to a separated component fluid receiver, said configuration comprising:

a separation layer having a fluid receiving area which is adapted to be disposed in fluid communication with a composite fluid source, said separation layer also having:

a fluid inlet channel;

a circumferential fluid separation channel; and,

at least one separated fluid outlet channel;

wherein said inlet channel is disposed in fluid communication with said fluid receiving area; and

wherein said circumferential separation channel is disposed in fluid communication with said fluid inlet channel and with each of said at least one separated fluid outlet channel; and

wherein each of said at least one separated fluid outlet channels is also adapted to be disposed in fluid communication with a corresponding separated component fluid receiver;

whereby said fluid inlet and each of said at least one fluid outlet channels also have respective inlet and outlet positions such that said positions are related to each other so as to provide fluid flow control in said separation layer.

2. A centrifugal configuration according to Claim 1 in which the relationship of the respective inlet and outlet positions of said inlet and said at least one separated fluid outlet channels to each other provides a fluid pressure imbalance.

3. A centrifugal configuration according to Claim 1 in which the relationship of the respective inlet and outlet positions of said inlet and said at least one separated fluid outlet channels to each other provides a fluid pressure imbalance which provides fluid flow control by

driving the flow of a composite fluid and at least one component thereof forward from the receiving area, respectively through the inlet, circumferential and at least one outlet channels.

4. A centrifugal configuration according to Claim 1 in which the relationship of the respective inlet and outlet positions of said inlet and said at least one separated fluid outlet channels to each other provides a fluid pressure imbalance for respective fluids flowing through the respective inlet and at least one outlet channels, and is defined as:

$$\rho_1 g_1 h_1 > \rho_2 g_2 h_2 \quad ;$$

wherein the first position, h_1 , represents the relative radial height of the inlet channel, and the second position, h_2 , represents the relative radial height of the at least one outlet channel, wherein g_1 and g_2 are centrifugal acceleration values and ρ_1 represents the density of the fluid in the inlet channel and ρ_2 represents the density of the fluid in the least one outlet channel.

5. A centrifugal configuration according to Claim 1 wherein the inlet position of the inlet channel is designated as h_1 and,

wherein the at least one outlet channel includes a first and a second outlet channel, and,

wherein the outlet position of the first outlet channel is h_2 , and the outlet position of the second outlet channel is h_3 , and,

wherein g_1 , g_2 and g_3 are centrifugal values, and,

ρ_1 represents the density of the fluid in the fluid inlet channel, ρ_2 represents the density of the fluid in the first outlet channel, and ρ_3 represents the density of the fluid in the second outlet channel, and,

whereby these structural values are related to each other such that the inlet channel fluid dynamic pressure, $\rho_1 g_1 h_1$, is greater than either of the two outlet fluid dynamic pressures, $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, as in:

$$\rho_1 g_1 h_1 > \rho_2 g_2 h_2 \quad \text{or,} \quad \rho_1 g_1 h_1 > \rho_3 g_3 h_3 \quad ;$$

so that fluid will flow from the fluid receiving area through the respective first and second outlet channels.

6. A centrifugal configuration according to Claim 5 wherein the ρgh values may be incrementally summed such that: $\Sigma(\rho gh)_1 > \Sigma(\rho gh)_2$, or, $\Sigma(\rho gh)_1 > \Sigma(\rho gh)_3$.

7. A centrifugal configuration according to Claim 5 wherein the ρ values are different for each term in the relationship such that the first ρ value, in $\rho_1 g_1 h_1$, is the density of the inlet composite fluid to be separated, whereas, the second and third ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of respective first and second separated fluid components.

8. A centrifugal configuration according to Claim 5 wherein the ρ values are different for each term in the relationship such that

the first ρ value, in $\rho_1 g_1 h_1$, is the density of the inlet composite fluid to be separated, whereas, the second and third ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of respective first and second separated fluid components, and whereby $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$ equalize with each other.

9. A centrifugal configuration according to Claim 5 wherein the composite fluid to be separated is blood and the ρ values are different for each term in the relationship such that the first ρ value, in $\rho_1 g_1 h_1$, is the density of a whole blood composite fluid, whereas, the second and third ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of respective separated blood components, particularly plasma and red blood cells (RBCs).

10. A centrifugal configuration according to Claim 5 wherein the ρ values are different for each term in the relationship such that the first ρ value, in $\rho_1 g_1 h_1$, is the density of the inlet composite fluid to be separated, whereas, the second and third ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of respective first and second separated fluid components; and

wherein the second ρ value, in $\rho_2 g_2 h_2$, includes first and second elements from the respective first and second separated fluid components, such that $\rho_2 g_2 h_2$ is the sum of $\rho_{1stcomponent} g_{1stcomponent} (h_2 - h_i)$ and $\rho_{2ndcomponent} g_{2ndcomponent} h_i$; wherein h_i is the height of the interface between the first and second separated fluid components.

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11. A centrifugal configuration according to Claim 9 wherein the composite fluid to be separated is blood and the ρ values are different for each term in the relationship such that the first ρ value, in $\rho_1 g_1 h_1$, is the density of whole blood, whereas, the respective first and second separated fluid ρ values, appearing in $\rho_{1stcomponent} g_{1stcomponent} (h_2 - h_i)$ and $\rho_{2ndcomponent} g_{2ndcomponent} h_i$; represent the densities of the separated components, plasma and red blood cells (RBCs), respectively.

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12. A centrifugal configuration according to Claim 1 in which the at least one outlet channel includes a first and a second outlet channel, and,

wherein the relationship of the respective first and second lengths of said first and second separated fluid outlet channels to each other provides a substantial fluid pressure balance for respective fluids flowing therethrough.

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13. A centrifugal configuration according to Claim 1 in which the at least one outlet channel includes a first and a second outlet channel, and,

wherein the relationship of the respective first and second lengths of said first and second separated fluid outlet channels to each other provides a substantial fluid pressure balance for respective fluids flowing through the respective first and second outlet channels, and is defined such that it provides fluid flow control of the interface of separated fluid components within the circumferential separation channel.

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14. A centrifugal configuration according to Claim 1 in which the at least one outlet channel includes a first and a second outlet channel, and,

wherein the relationship of the respective first and second lengths of said first and second separated fluid outlet channels to each other provides a substantial fluid pressure balance for

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respective fluids flowing through the respective first and second outlet channels, and is defined as:

$$\rho_2 g_2 h_2 = \rho_3 g_3 h_3$$

wherein the first length of the first outlet channel is h_2 , and the second length of the second outlet channel is h_3 , wherein g is a gravitational acceleration value and ρ_2 represents the density of the fluid in the first outlet channel and ρ_3 represents the density of the fluid in the second outlet channel.

15. A centrifugal configuration according to Claim 14 wherein the $\rho g h$ values may be incrementally summed such that: $\Sigma(\rho g h)_2 = \Sigma(\rho g h)_3$.

16. A centrifugal configuration according to Claim 14 in which the composite fluid to be separated is blood and the first and second separated components are plasma and red blood cells (RBCs), respectively.

17. A centrifugal configuration according to Claim 14 in which the ρ_2 value in the $\rho_2 g_2 h_2$ term has two distinct components derived from a combination of separated fluid component terms such that $\rho_2 g_2 h_2$ is the sum of $\rho_{1stcomponent} g_{1stcomponent} (h_2 - h_i)$ and a $\rho_{2ndcomponent} g_{2ndcomponent} h_i$; whereby h_i is the height of the interface between the first and second separated fluids, and,

$$\rho_2 g_2 h_2 = \rho_{1stcomponent} g_{1stcomponent} (h_2 - h_i) + \rho_{2ndcomponent} g_{2ndcomponent} h_i = \rho_{2ndcomponent} g_{2ndcomponent} h_3 = \rho_3 g h_3 .$$

18. A centrifugal configuration according to Claim 14 in which the composite fluid to be separated is blood and the first and second separated components are plasma and red blood cells (RBCs); and,

wherein the ρ_2 value in the $\rho_2 g h_2$ term has two distinct components derived from a combination of separated fluid component terms, thus having a plasma and an RBC component

such that $\rho_2 g_2 h_2$ is the sum of $\rho_{\text{plasma}} g_{\text{plasma}} (h_2 - h_i)$ and a $\rho_{\text{RBC}} g_{\text{RBC}} h_i$ portion; wherein h_i is the height of the interface between the RBCs and the plasma, and,

$$\rho_2 g_2 h_2 = \rho_{\text{plasma}} g_{\text{plasma}} (h_2 - h_i) + \rho_{\text{RBC}} g_{\text{RBC}} h_i = \rho_{\text{RBC}} g_{\text{RBC}} h_3 = \rho_3 g_3 h_3 .$$

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19. A centrifugal configuration according to Claim 14 wherein the inlet position of the inlet channel is designated as h_1 and wherein the first outlet position of the first outlet channel is h_2 , and the second outlet position of the second outlet channel is h_3 , wherein g_1 , g_2 and g_3 are centrifugal values and ρ_1 represents the density of the fluid in the fluid inlet channel, ρ_2 represents the density of the fluid in the first outlet channel, and ρ_3 represents the density of the fluid in the second outlet channel and these values are related to each other such that the inlet fluid dynamic pressure, $\rho_1 g_1 h_1$, is greater than the either of the two outlet fluid dynamic pressures, $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, as in:

$$\rho_1 g_1 h_1 > \rho_2 g_2 h_2 \quad \text{or} \quad \rho_3 g_3 h_3$$

so that fluid will flow from the inlet toward the outlets.

20. A centrifugal configuration according to Claim 19 wherein the ρ values are different for each term in the relationship such that the first ρ value, in $\rho_1 g_1 h_1$, is the density of the inlet composite fluid to be separated, whereas, the second and third ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of the respective first and second separated fluid components.

21. A centrifugal configuration according to Claim 18 wherein the composite fluid to be separated is blood and the ρ values are different for each term in the relationship such that the first ρ value, in $\rho_1 g_1 h_1$, is the density of whole blood, whereas, the second and third ρ values, appearing in $\rho_2 g_2 h_2$ and $\rho_3 g_3 h_3$, represent the densities of the first and second separated components, plasma and red blood cells (RBCs).

22. A centrifugal configuration according to Claim 1 in which the configuration further includes an outlet layer which is disposed in fluid communication with said at least one outlet channel.

5 23. A centrifugal configuration according to Claim 22 in which the outlet layer is disposed below the separation layer.

24. A centrifugal configuration according to Claim 22 in which the outlet layer is disposed above the separation layer.

10 25. A centrifugal configuration according to Claim 22 in which the at least one outlet channel includes a first and a second outlet channel and each said first and a second outlet channel are disposed in discrete fluid communication with the outlet layer from the separation layer.

15 26. A centrifugal configuration according to Claim 22 in which the outlet layer is a first outlet layer and in which the configuration further includes a second outlet layer; and in which the at least one outlet channel includes first and a second outlet channels; whereby the first outlet channel is disposed in fluid communication with said first outlet layer and said second outlet channel is disposed in fluid communication with said second outlet layer.

20 27. A centrifugal configuration according to Claim 26 in which the first outlet layer is disposed below the separation layer and the second outlet layer is disposed above the separation layer.

25 28. A centrifugal configuration according to Claim 26 in which the first and second outlet layers are disposed below the separation layer.

30 29. A centrifugal configuration according to Claim 26 in which the first and second outlet layers are disposed above the separation layer.

30. A centrifugal configuration according to Claim 22 in which the outlet layer is disposed in fluid communication with at least one outlet conduit member which is adapted to be disposed in fluid communication with a storage container.

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31. A centrifugal configuration according to Claim 30 in which the at least one outlet channel includes a first and a second outlet channel and each said first and a second outlet channel is disposed in discrete fluid communication with the outlet layer; and wherein said at least one outlet conduit member includes first and second outlet conduit members each of which being in discrete fluid communication with the respective first and second outlet channels, and adapted to be disposed in fluid communication with respective first and second storage containers.

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32. A centrifugal configuration according to Claim 22 whereby said at least one separated fluid outlet channel is also adapted to be disposed in fluid communication with a corresponding separated component fluid receiver.

33. A centrifugal configuration according to Claim 32 in which the configuration delivers the separated fluid component to said at least one separated fluid outlet channel such that the separated fluid component retains kinetic energy to flow to the corresponding separated component fluid receiver.

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34. A centrifugal configuration according to Claim 33 in which the configuration has a vortex pump configuration such that the kinetic energy is retained by action of the vortex pump configuration.

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35. A centrifugal configuration according to Claim 32 in which the configuration delivers the separated fluid component to said at least one separated fluid outlet channel by gravity drainage of the separated fluid component to the corresponding separated component fluid receiver.

36. A centrifugal configuration according to Claim 1 in which the configuration further includes a second inlet channel; a second circumferential channel and a second at least one outlet channel;

whereby said second inlet channel is disposed in fluid communication with said fluid receiving area; and

wherein said second circumferential channel is disposed in fluid communication with said second fluid inlet channel and with each of said second at least one separated fluid outlet channel; and

wherein each of said second at least one separated fluid outlet channels is also adapted to be disposed in fluid communication with a corresponding separated component fluid receiver;

whereby said second inlet and each of said second at least one fluid outlet channels also have respective lengths such that said lengths are related to each other so as to provide fluid flow control in said separation layer.

37. A centrifugal configuration according to Claim 36 in which the receiving area of said configuration further includes a septum which divides said receiving area into first and second parts, said first part being in fluid communication with the first inlet channel and the second part being in fluid communication with the second inlet channel.

38. A centrifugal configuration according to Claim 36 in which the second inlet channel; the second circumferential channel and the second at least one outlet channel are disposed in said configuration so as to provide a weight balance to said configuration relative to said first inlet channel and the first circumferential channel and the first at least one outlet channel.

39. A centrifugal configuration according to Claim 38 in which the second inlet channel; the second circumferential channel and the second at least one outlet channel are disposed diametrically opposite said first inlet channel; the first circumferential channel and the first at least one outlet channel.

40. A centrifugal configuration according to Claim 1 in which said configuration further includes a balance channel which is disposed in fluid communication with the circumferential channel;

5 whereby said balance channel may provide a weight balance to said configuration relative to said inlet channel and the at least one outlet channel.

41. A centrifugal configuration according to Claim 40 in which said balance channel which is disposed in fluid communication with an outlet layer.

10 42. A centrifugal configuration according to Claim 41 in which said balance channel which is an outlet channel which provides for flow of a separated component fluid therethrough.

15 43. A centrifugal configuration according to Claim 42 in which said circumferential channel is of a first width adjacent the inlet channel and is of a second wider width adjacent the balance channel.

20 44. A centrifugal configuration according to Claim 42 in which said circumferential channel is of a first width adjacent the inlet channel and is of a second wider width at a substantially diametrically opposed portion of said circumferential channel.

25 45. A centrifugal configuration according to Claim 1 in which the at least one outlet channel includes first and second outlet channels and the configuration further includes an interface wall disposed in said circumferential channel between said first and second outlet channels.

46. A centrifugal configuration according to Claim 1 in which the configuration is comprised within a rotor.

47. A centrifugal configuration according to Claim 46 in which the rotor is comprised within a housing, said rotor and housing being a centrifuge unit.

48. A centrifugal configuration according to Claim 46 in which the rotor is comprised within a housing, said rotor and housing being a disposable centrifuge unit.

49. A centrifugal configuration according to Claim 46 in which the rotor is comprised within a housing, said rotor and housing being a centrifuge unit;
whereby said centrifuge unit has connected thereto at least one tubing line.

50. A centrifugal configuration according to Claim 49 in which said centrifuge unit has connected thereto at least one inlet tubing line.

51. A centrifugal configuration according to Claim 49 in which said centrifuge unit has connected thereto at least one outlet tubing line.

52. A centrifugal configuration according to Claim 51 in which said outlet tubing line has connected thereto at least one storage container.

53. A centrifugal configuration according to Claim 49 in which said centrifuge unit has connected thereto at least first and second outlet tubing line.

54. A centrifugal configuration according to Claim 53 in which each said first and second outlet tubing lines has connected thereto respective first and second storage containers.

55. A centrifugal configuration according to Claim 49 in which said centrifuge unit has connected thereto at least one inlet tubing line.

56. A centrifugal configuration according to Claim 55 in which said inlet tubing line has connected thereto at least one access device.

57. A centrifugal separation system for use in a fluid separation system to centrifugally separate a composite fluid into composite components thereof, said centrifugal separation device comprising:

5 a centrifugal drive motor base;

a centrifugal rotor housing which is adapted to be disposed in an operable rotor-driving position on said centrifugal drive motor base, said housing having a fluid inlet port and at least one fluid outlet port; and,

10 a rotor disposed in a freely rotatable position within said housing, said rotor having a fluid receiving area which is disposed in fluid communication with the fluid inlet port of said rotor housing, said rotor also having a fluid inlet channel, a circumferential fluid separation channel and first and second separated fluid outlet channels, wherein said inlet channel is disposed in fluid communication with said fluid receiving area and wherein said circumferential separation channel is disposed in fluid communication with said fluid inlet channel and said first and second separated fluid outlet channels, at least one of said first and second separated fluid outlet channels also being disposed in fluid communication with said at least one fluid outlet port of said housing;

20 said first and second fluid outlet channels also having respective first and second lengths wherein said lengths are related to each other so as to provide a substantial hydraulic balance for respective fluids flowing therethrough.

58. A centrifugal separation system according to claim 57 in which the centrifugal drive motor base produces a rotating magnetic field, and wherein said rotor contains a magnetically reactive material which is adapted to rotate with the rotating magnetic field produced by said motor base, whereby said rotor is caused to rotate by the co-action of said magnetically reactive material and said rotating magnetic field.

59. A centrifugal separation device according to claim 57 in which the centrifugal drive motor base has a flat top surface, and the rotor housing has a flat bottomed surface, whereby the flat top surface of the drive motor base and the flat bottomed surface of the rotor housing co-act

to provide the adaptation of the rotor housing to be disposed in operable rotor-driving position on said centrifugal drive motor base.

60. A separation device comprising:

a rotor having an axial, a radial and a circumferential orientation;

wherein said rotor has a circumference and is rotatable about said axial orientation;

a housing in which said rotor is disposed;

whereby said housing has an inlet opening and at least one outlet opening; said inlet opening being disposed substantially perpendicular to the plane of rotation of said rotor;

said outlet opening being disposed substantially tangential to said circumference of said rotor.

61. A composite fluid separation device comprising:

a rotor having an axial, a radial and a circumferential orientation; wherein said rotor has a circumference and is rotatable about said axial orientation;

said rotor also having

a substantially centrally-disposed containment pocket,

an inlet channel communicating with said containment pocket,

a peripheral channel communicating with said inlet channel, and

an outlet channel communicating with said peripheral channel,

whereby the outlet channel is adapted to be connected in fluid communication with a collection container;

whereby said inlet channel has a representative height h_c and the outlet channel has a representative height h_1 ; and

height h_c and height h_1 are related to each other such that

$$h_c > h_1 \quad .$$

62. A composite fluid separation device according to claim 61 in which said rotor further comprises:

a second outlet channel communicating with said peripheral channel, and
whereby the second outlet channel is adapted to be connected in fluid communication
with a second collection container;

whereby said second outlet channel has a representative height h_2 ; and

whereby the height h_c and the heights h_1 and h_2 are related to each other such that

$$h_c > h_1 \text{ or } h_2 .$$

63. A composite fluid separation device according to claim 61 in which said rotor further
comprises:

a second outlet channel communicating with said peripheral channel, and

whereby the second outlet channel is adapted to be connected in fluid communication
with a second collection container;

whereby said second outlet channel has a representative height h_2 ; and

whereby the heights h_1 and h_2 are related to each other such that

$$h_1 = h_2 .$$

64. A disposable rotor, tubing and container system for use in the separation of a composite fluid
into separated components, the disposable system comprising:

a disposable centrifuge unit having a housing and a rotor disposed in freely rotatable
disposition within said housing;

a first separated component container; and

a tubing line;

whereby said first separated component container is connected to said disposable
centrifuge unit by the tubing line.

65. A disposable system according to claim 64 in which the centrifuge unit is connected to an
access line which may be used to connect the system to a donor/patient.

66. A disposable system according to claim 64 which further comprises
a second separated component container; and
whereby said second separated component container is connected to said centrifuge unit
by a second tubing line.

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67. A disposable system according to claim 64 in which said rotor is constructed of substantially
rigid materials.

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68. A disposable system according to claim 67 in which said rotor is constructed from injection-
molded plastic.

69. A disposable system according to claim 67 in which said rotor is constructed from blow-
molded plastic.

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70. A method for separating a composite fluid into component parts comprising:

providing a rotor configuration having:

a rotor which includes;

a composite fluid containment area;

a fluid inlet channel;

a peripheral fluid separation channel; and

first and second separated fluid outlet channels;

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wherein said inlet channel is disposed in fluid communication with said fluid containment
area; and wherein said peripheral separation channel is disposed in fluid communication with
said fluid inlet channel and said first and second separated fluid outlet channels; and wherein said
first and second separated fluid outlet channels are adapted to be disposed in fluid
communication with discrete first and second separated component storage containers; and

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whereby said inlet channel and said first and second separated fluid outlet channels also
have respective inlet and first and second outlet heights wherein said heights are related to each
other so as to provide a substantial fluid pressure flow control for respective composite and
separated components flowing therethrough; and

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delivering a composite fluid to the composite fluid containment area of said rotor configuration; and
rotating said rotor configuration to separate said composite fluid into its component parts.

5 71. A method according to Claim 70 which further includes collecting said separated components.

72. A method according to Claim 70 which further includes automatically driving the flow through said separation channel.

10 73. A method according to Claim 70 which further includes automatically shutting off the flow through said separation channel.

74. A method according to Claim 70 which further includes automatically readjusting the flow in and through said separation channel by automatically equalizing fluid pressure in the first and second separated fluid outlet channels.

75. A method according to Claim 70 which further includes automatically capturing an intermediate phase component in said separation channel by automatically shutting off the flow out of said separation channel after collection of said first and second separated components when a there remains no more composite fluid to be separated.

76. A method according to Claim 70 which further includes: using a disposable rotor configuration.